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October 21, 2005

Division of Docket Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: Docket #2005P-0411: Pharmacy compounding of women's hormonal products.

To Whom It May Concern:

This note is in support of the aforementioned FDA petition to further regulate hormones compounded by local pharmacies.

These estrogen products are widely promoted as being safe and effective. They are marketed on an informal basis directly to the patient, who in turn requests their physician to write an appropriate prescription. Often, the patient is interviewed by the pharmacist and a suitable prescription is faxed to the physician, who only has to sign the prescription and fax it back to the pharmacy for it to be a valid prescription.

This is done without the patient being advised that similar products are available as a generic or commercially manufactured item. Attached is a copy of such a prescription sent to me on the behalf of one of my patients. It is probably worth noting on this prescription that both estriol and pregnenolone are not commercially available in any current products. I, in particular, did a literature search through the Ohio Northern University Drug Information Center regarding pregnenolone recently: I cannot find any published literature on its use in humans over the past 20 years.

Certainly, estrogen replacement is oversold by compounding pharmacies. No reliable studies have been performed to show that this is as good as regimens that are commercially available. These products are marketed to busy physicians in such a way that the physician has no idea of the potential risks involved with concocting a new hormone product from scratch.

Please feel free to call or write should I be of any assistance or to clarify the above points.

Respectfully,

Bruce A. Bouts, R.Ph., M.D., F.A.C.P.

BAB/sr
Enc.

2005P-0411

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SCARBROUGH MEDICAL ARTS PHARMACY
1809 SOUTH MAIN STREET
FINDLAY, OHIO 45840
"COMPOUNDING SPECIALISTS SINCE 1996"

Dear Doctor Bouts:

Hello, I'm Stan Scarbrough with Scarbrough Medical Arts & Compounding Pharmacy. I realize your time is valuable, however I would greatly appreciate a few moments to introduce you to the newest concept in prescription hormone replacement therapy.

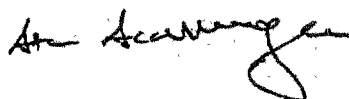
As you know, today's healthcare consumer is taking a more active role in their search for quality outcomes. This activity is challenging the medical community in several areas. One such area of increasing demand is that of *Hormonal Replacement Therapy*. The associates at Scarbrough Compounding Pharmacy have taken an active role as part of the healthcare team to increase our working knowledge of current therapies and patient specific formulations. The associates at Scarbrough Compounding Pharmacy have become leaders in working with physicians to help women with their hormone replacement options. It is our goal to provide educational material and patient-specific formulations to clarify and optimize any *Hormonal Replacement Therapy* that might be utilized.

Prescription *natural bio-identical hormone replacement therapy* offers many options. We feel it is very important for patients to understand these options, to become educated on this topic, and to discuss this in great detail with their doctor. This is the specific reason for our communication with you today. One of your patients has chosen to pursue RxNHRT as an option, and we have met to review some information. Included in this letter are some specific data we have collected, and some detailed recommendations we have developed for your review. We recognize that as this patient's physician, the final decision to implement therapy is with you and ultimately, the patient. We appreciate the opportunity to participate in this process, and look forward to hearing back from you regarding these options presented.

Thank you for your time in reviewing this information. We look forward to working with you and your patients in meeting their individual needs and in helping them receive the most benefit from whatever therapy is selected. We appreciate the opportunity to offer you products and services "beyond the common place."

Doctor Bouts, thank you for allowing us to assist you with your patient B. Gale Palmer. We will inform her to keep you apprised as to how she is feeling, and we will relay any information to you, should we hear anything from her. We continually follow up with our BHRT patients, we will forward any gathered information to your office.

Sincerely,



Compounding Specialist
Scarbrough Pharmacy